



(11) Publication number:

0 315 440 B1

(12)

EUROPEAN PATENT SPECIFICATION

(13) Date of publication of patent specification: **02.06.93** (51) Int. Cl.⁵: **B65D 81/32, B65D 25/08**

(21) Application number: **88310327.7**

(22) Date of filing: **02.11.88**

(54) **A dual-chambered mixing and dispensing vial.**

(30) Priority: **06.11.87 GB 8726062**

(43) Date of publication of application:
10.05.89 Bulletin 89/19

(49) Publication of the grant of the patent:
02.06.93 Bulletin 93/22

(84) Designated Contracting States:
AT BE CH DE ES FR GB GR IT LI LU NL SE

(66) References cited:
FR-A- 2 239 390
FR-A- 2 319 544
US-A- 4 606 734

(73) Proprietor: **MERCK & CO. INC.**
126, East Lincoln Avenue P.O. Box 2000
Rahway New Jersey 07065-0900(US)

(72) Inventor: **Henault, Paul**
58 Rue des Mauvaises Cabazat
F-63100 Clermont-Ferrand(FR)
Inventor: **Lataix, Gilbert**
19 Chemin de la Conche
F-63140 Chatel-Guyon(FR)
Inventor: **Macartney, Carleton H.**
38 Redfield Road
Lincroft New Jersey 07738(US)
Inventor: **Saffron, Ronald**
Linley Farm, East Knoyle,
Salisbury, Wiltshire,(GB)

(74) Representative: **Cole, William Gwyn et al**
European Patent Department, Merck & Co.,
Inc., Terlings Park, Eastwick Road
Harlow, Essex CM20 2QR (GB)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Description

BACKGROUND OF THE INVENTION

This invention relates to fluid dispensing devices in which constituents of the fluid mixture can be maintained in separate chambers and in which the separated constituents can be mixed *in vitro*, when desired, by placing the chambers in communication with one another. A dislodgeable stopper serves to maintain separation of mixture components in the two chambers, which can be dislodged by a plunger within one chamber which is activated by the depression of the flexible walls of one of the chambers.

Container devices having multiple compartments for separately enclosed materials to be mixed prior to use are described in U.S. Pat. Nos. 3 340 873, 3 354 883, 3 397 894, 3 411 503, 4 331 146, 4 412 836, and 4 330 531, having a thin diaphragm-type membrane separating the two compartments. These systems are not considered entirely reliable because of their inability to maintain a fluid-tight seal between the compartments. U.S. Pat. No. 3 464 414 discloses a rigid walled two chambered mixing vial utilizing hydraulic pressure to dislodge a plug member between the two chambers.

FR-A-2319544 discloses a dual chamber mixing and dispensing device wherein the contents of each chamber are maintained separate from one another by means of a sealing stopper. In order to mix the separated contents, the sealing stopper is completely dislodged by means of a rod encased in a compressible sleeve. After the contents are mixed, they can be withdrawn from the device by means of a needle which is inserted into the stopper through a target zone or by inserting the needle through zone of hollow tube or rod.

In US-A-4 606 734 there is disclosed an intravenous bag consisting of a flexible plastic container connected to an external, additive assembly which contains medication to be added to the plastic, intravenous container. Medication from additive assembly is added to the plastic, intravenous container when bellows (43) is depressed so that pin having an internal passageway pierces stopper and diaphragm enabling the medication to flow into intravenous container.

SUMMARY OF THE INVENTION

The present invention relates to a dispensing device adapted to hold two substances which are required to be segregated until just prior to dispensation, and to provide a means for *in vitro* mixing and dispensing of the mixture. Thereby, a mixture having a limited effective life once mixed may be

preserved indefinitely by maintaining separate components until use is desired. While one of the constituents must be liquid the other component may be a liquid or a solid.

The dispenser comprises two vertically spaced compartments separated by a valve which can selectively be operated by the user by movement of one compartment towards or away from the other. In use, the dispenser may be presented to a patient with the valve closed to prevent mixing of the two retained substances and to maintain sterility of the constituents.

The valve is operated manually by the patient and the dispenser either inverted or shaken to cause the until now separated substances to mix.

The body of the dispenser, which may be provided with a removable cap, can thereafter be squeezed thereby causing droplet, flow or jet of mixed fluid to be emitted from an outlet nozzle of the dispenser. Alternatively, the dispenser includes a septum to permit withdrawal of the mixed substances using a hypodermic needle or the like.

In a preferred construction, the first compartment is positioned above the second compartment, the two being separated by the common wall which includes a seating for a valve; the boundary wall of the second compartment is capable of movement in a direction towards and/or away from the first compartment and the valve includes a valve stem which is engaged by movement of the second compartment to lift the valve away from its seating to enable substances present in the compartments to be mixed.

The second compartment may comprise a flexible structure capable of flexing in the required manner. In a preferred embodiment, the compartment takes the form of a bellows-like member.

Alternatively, the walls of the second compartment comprise a flexible diaphragm or a plastic bulb capable of returning to its original shape and configuration after movement towards the first compartment.

Accordingly, it is an object of this invention to provide a dual chambered mixing and dispensing vial, operable without the limitations presented in the prior art.

It is another object of this invention to provide a dual chambered mixing and dispensing medicinal vial that is operable by a patient in need of medication comprised of components which must be segregated until use is required.

It is a further object of this invention to provide a dual chambered mixing and dispensing device adaptable to be used with a variety of dispensing means.

Additional objects of this invention will be apparent to persons of ordinary skill in the art upon reading the following detailed description and ap-

pendent claims and upon reference to the accompanying drawings.

DETAILED DESCRIPTION OF THE INVENTION

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the invention reference should be made to the embodiment illustrated in greater detail in the accompanying drawings and described below by way of example of the invention. In the drawings:

Figure 1 is a cross-sectional view of the mixing and dispensing device of this invention, being shown prior to the removal of the protective base cap and being shown with a dropper tip dispenser.

Figure 2 is a cross-sectional view of the embodiment of Figure 1 of this invention, being shown with the protective base cap removed and with the stem activated.

Figure 3 is a cross-sectional view of the embodiment of Figure 1 of this invention, being shown after the activation of the stem.

Figure 4 is a cross-sectional view of the embodiment of Figure 1 of this invention being shown with a septum dispenser.

Figure 5 is a partial cross-sectional view of an alternative embodiment of the invention.

Figure 6 is a cross-sectional view of another alternative embodiment of the invention.

As can be seen in Figures 1-3, one embodiment of the mixing and dispensing device of this invention includes a body portion 1 into the upper rim of which is attached nozzle 2. While any suitable means of impermeable attachment may be used, electromagnetic welding is effective for plastic components. The nozzle 2 is provided with external screw threads 3 to receive internal screw threads 4 of a closure cap 5. As illustrated in the embodiment of Figures 1-3 the lower end 6 of the nozzle 2 protrudes downwardly into a generally cylindrical neck 7 for ease of dispensing. It is to be understood, however, that any conventional form of the nozzle may be employed.

The body portion 1, base member 8 and the nozzle 2 essentially define the boundaries of first compartment 9. Protruding downward from base member 8, and parallel to body portion 1 is cylindrical skirt 10. Positioned within and contacting the internal surface of the skirt 10 is ring member 11. Securedly fitted between the upper rim of ring member 11 and the underside of base member 8 is an outwardly extending flange 12 of a vertically flexible bellows 14. This bellows 14, along with the underside of base member 8 defines the second compartment of the mixing and dispensing device. The flange 12 is held in place by a suitable means

of attachment, preferably by electro-magnetic welding.

Positioned between the first and second compartments is a valve 16 which fits securely within a cylindrical collar 17 projecting upward from base member 8 into the first compartment 9. Projecting downward from the valve 8 into the second compartment 15 is stem 18. Stem 18 protrudes into the compartment to a position close to or in contact with the bottom of bellows 14.

A rigid, removeable cylindrical base cap 19 closes off the lower portion of the mixing and dispensing vial by fitting onto the ring member 11 up to the point where it meets skirt 10. This base cap may be held in place by any reliable but removeable, securing means, such as push-fitting, screw threading, and the like. Tamper proof means, such as a shrink wrap coating may also be used to prevent inadvertent removal of the base cap. Although it is contemplated that the various components of this dispenser are preferably manufactured from plastic material, any suitable material may be used for one or more of the members.

As illustrated in Figure 2, when mixture of the components is desired, the base cap 19 is removed, and the bellows 14 is depressed toward the first compartment, thereby raising valve stem 18 and, in turn, dislodging valve 16 from its secured position inside collar 17. Once the valve is dislodged the segregated components can readily mix. This mixture may be facilitated by hydraulic pressure created by the depression and expansion of the bellows 14, or by manually shaking the dispenser. The valve stem is designed so that its cross-sectional area is less than the cross-sectional area of the orifice formed by collar 17, so that communications can occur between the two compartments even when valve stem 18 is situated within the orifice. An "X" shaped cross-section design of the valve stem as can be seen in Figures 1-3 has proven effective.

The dispenser may contain in the first compartment a sterile powder, while in the second compartment a sterile diluent. Alternatively, two sterile liquids may be maintained in the separate compartments until mixture is desired.

As illustrated in Figure 3, once the constituents are mixed, the closure cap 5 may be removed from nozzle 2 to permit dispensing of the mixture as droplets or as liquid streams or jets.

Figure 4 illustrates an alternative embodiment of the mixing and dispensing device of this invention. In this embodiment, ring member 11 has been eliminated, and base cap 19 is designed with inner lip 27 to securedly fit within the lower end of the dispenser wall. Also in this illustration the nozzle dispenser means has been replaced with a stopper 21 produced from a flexible material such as rub-

ber. Until dispensing of the mixture is desired, the upper surface of stopper 21 is secured by an aluminum seal 22 and the dispenser is closed by a removeable cap 23. The seal 22 and rubber stopper 21 define a septum into and through which a hypodermic needle may be inserted to withdraw a dose of the mixture.

The mixing operation of the dispensing device illustrated in Figure 4 is similar to that described in the context of Figures 1-3. However, after mixing and/or dissolving of the components, the cap 23 is removed to expose the upper surface of the aluminum seal 22. A hypodermic needle may then be inserted through the stopper 21, to enable the extraction of a desired dose of the mixture from the dispenser.

In the arrangement illustrated in Figure 5, the bellows member 14 of the previous illustrations has been replaced with a flexible diaphragm 24 dependent from an upper annulus 25. The annulus should be thicker or otherwise substantially non flexible as compared to the flexible diaphragm. In other respects the construction and operation of the dispensing device of Figure 5 is similar to that described above with respect to the embodiment of Figures 1-3.

The embodiment of dispensing device illustrated in Figure 6 is similar to that illustrated in Figure 5 excepting that, in this embodiment, the lower compartment takes the form of a bulb 26 of plastic material. In this embodiment the dimensions and size of the bulb 26 are such that the bulb returns to its original shape and configuration after initial movement of it towards the upper compartment 9 to operate the valve 16. Thus, in use, and after mixing of the substances contained in the two compartments, the bulb can operate as a dropper mechanism.

It is to be understood that the present invention has been described above purely by way of example and that modifications of detail can readily be made thereto within the scope and spirit of the invention.

Thus, in the embodiment of Figures 1 to 3, the member 14 may comprise any construction which facilitates movement of the compartment 15 in a direction towards and/or away from the compartment 9. Thus, compartment 15 may comprise two or more members which can slide one within the other to achieve the required "collapsing" or "expanding" movement.

Claims

1. A dual chamber mixture dispensing device having vertically aligned upper (9) and lower (15) chambers capable of communicating with each other, the device consisting of:

- (a) an upper chamber (9), the walls of which comprise a rigid body portion (1) having a droplet dispensing nozzle (2) secured to its upper end;
- (b) a lower chamber (15) having flexible walls defined by depressible bellows (14), said bellows (14) being surrounded by a cylindrical skirt (10) extending downwards from the body portion (1), a portion of said bellows (14) extending beyond the lower rim of said skirt (10);
- (c) a base cap member (19) removably attached to said skirt (10) and enclosing the extending portion of said bellows (14);
- (d) a transversely disposed common wall (8) separating said upper chamber (9) and said lower chamber (15), said common wall (8) having an orifice formed therein framed by a cylindrical collar (17) that protrudes upwardly into said upper chamber (9); and
- (e) valve means (16) removably seated in said cylindrical collar (17), said valve means (16) having a stem (18) depending therefrom into said bellows (14).

Patentansprüche

1. Misch- und Ausgabeeinrichtung mit zwei Kammern, welche vertikal ausgerichtete obere (9) und untere (15) Kammern hat, welche in kommunizierende Verbindung miteinander bringbar sind, wobei die Einrichtung folgendes umfaßt:
 - (a) eine obere Kammer (9), deren Wände einen starren Körperabschnitt (1) aufweisen, der eine Tropfenausgabeeüse (2) hat, die fest an seinem oberen Ende angebracht ist;
 - (b) eine untere Kammer (15), welche von einem zusammendrückbaren Balg (14) gebildete flexible Wände hat, wobei der Balg (14) von einem Zylindrischen Rand (10) umgeben ist, welcher sich von dem Körperabschnitt (1) nach unten erstreckt, und wobei ein Abschnitt des Balgs (14) sich über die untere Randzone des Rands (10) hinaus erstreckt;
 - (c) ein Bodenkappteil (19), welches lösbar an dem Rand (10) angebracht ist und den verlängerten Teil des Balgs (14) umschließt;
 - (d) eine in Querrichtung angeordnete, gemeinsame Wand (8), welche die obere Kammer (9) und die untere Kammer (15) voneinander trennt, wobei die gemeinsame Wand (8) eine Öffnung hat, welche darin ausgebildet ist und durch einen zylindrischen Bund (17) eingefaßt ist, welcher in die obere Kammer (9) nach oben vorsteht; und

(e) eine Ventileinrichtung (16), welche lösbar in dem zylindrischen Bund (17) sitzt, wobei die Ventileinrichtung (16) einen davon nach unten in den Balg (14) weisenden Schaft (18) hat.

5

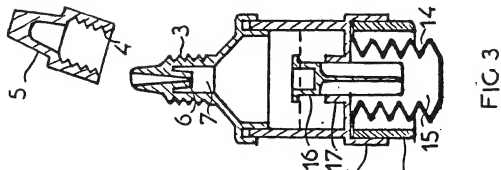
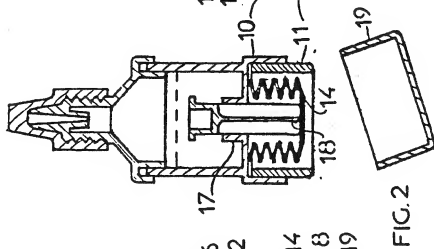
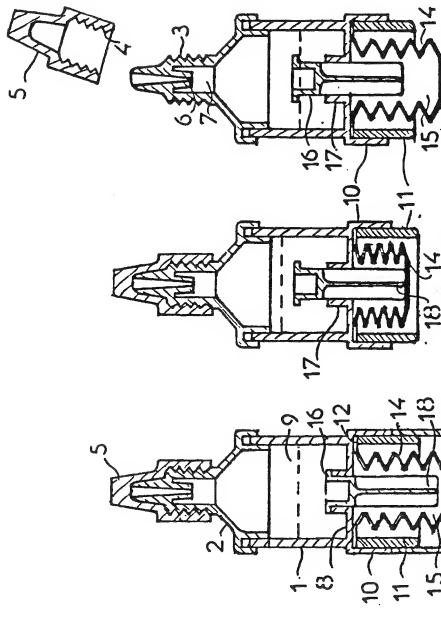
Revendications

1. Dispositif à deux compartiments pour la distribution d'un mélange ayant des compartiments supérieur (9) et inférieur (15) alignés verticalement capables de communiquer l'un avec l'autre, le dispositif étant constitué par :
 - (a) un compartiment supérieur (9), dont les parois comprennent une partie formant un corps rigide (1) ayant un embout de distribution de gouttes (2) fixé à son extrémité supérieure; 10
 - (b) un compartiment inférieur (15) ayant des parois flexibles définies par des soufflets compressibles (14), lesdits soufflets (14) étant entourés d'une jupe cylindrique (10) s'étendant vers le bas à partir de la partie formant le corps (1), une partie desdits soufflets (14) s'étendant au-delà du bord inférieur de ladite jupe (10); 15
 - (c) une pièce formant couvercle de la base (19) fixée de façon amovible à ladite jupe (10) et enfermant la partie en extension desdits soufflets (14); 20
 - (d) une paroi commune disposée transversalement (8) séparant ledit compartiment supérieur (9) et ledit compartiment inférieur (15), ladite paroi commune (8) ayant un orifice formé dans celle-ci encadré par un collier cylindrique (17) qui fait saillie vers le haut dans le compartiment supérieur (9); et 25
 - (e) un moyen formant valve (16) logé de façon amovible dans ledit collier cylindrique (17), ledit moyen formant valve (16) ayant une tige (18) dépendant de celui-ci, dans lesdits soufflets (14). 30

45

50

55



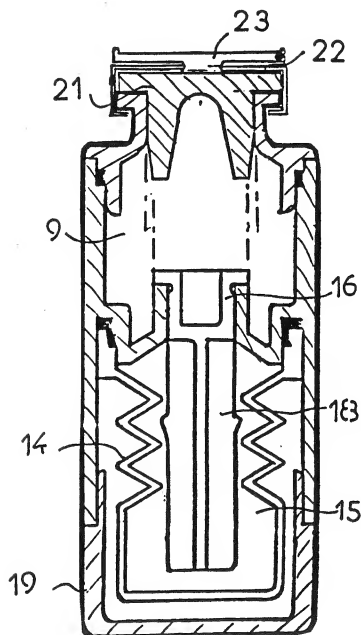


FIG. 4

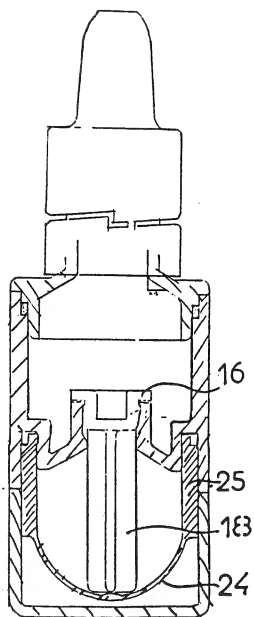


FIG 5

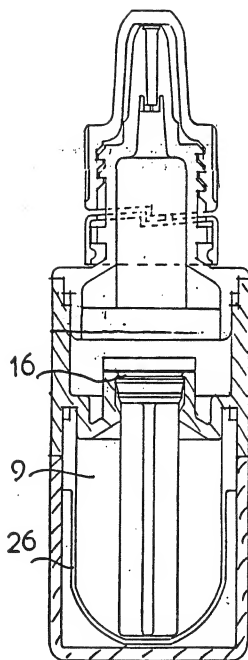


FIG 6